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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,167	02/02/2004	John Brassil	040219.04	6029

7590 12/03/2007

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EXAMINER	
SAUCIER, SANDRA E	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
12/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/768,167

Applicant(s)

BRASSIL ET AL.

Examiner

Sandra Saucier

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/2/04, 11/10/05, 8/31/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-18 are pending and are considered on the merits.

Election/Restriction

Applicants' arguments have been carefully considered and found to be persuasive. The restriction requirement is withdrawn and Groups I and II are rejoined and examined on the merits.

Information Disclosure Statement

The prior paper-based applications were obtained by the examiner and the paper files were searched for the references contained therein. Numerous references are no longer associated with 09/645525 or 09/162128, both of which are paper files or with 09/537180 or 10/617130 which have been scanned and are IFW files. Those references no longer associated with the files have been lined through. Numerous US Patents were duplicate citations and the duplicate has been lined through and either "duplicate" or "dup" has been written in the line.

References 20, 23 have no date, no journal, see references cited on IDS for particulars. References 20 and 23 have therefore been lined through.

The listing of the references on PTO 1449 is incomplete. A proper citation includes AUTHOR, TITLE, JOURNAL, VOLUME, NUMBER, INCLUSIVE PAGES, (month), YEAR. The citation is missing the author and title of the article.

MPEP37 CFR 1.98(b) requires that each publication must be identified by author (if any), title, relevant pages of the publication, date and place of publication. The place of publication refers to the name of the journal, magazine, or other publication in which the information being submitted was published.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 uses the term "exposing". This term is indefinite because it cannot be determined if contact is made between the organ the substance or if the substance merely has to be present in the room to fulfill the claim limitation.

Claims 13-15 recite that "the sensed characteristics relate to ...". It cannot be determined what degree of relationship is required because all characteristics of the organ may be said to be related to one another as the organ is an isolated, discrete functioning unit and is being maintained in a metabolically active state.

The "sensing" is performed by a sensor, which is interpreted to be a type of transducer, in claim set 1-15, while in claim set 16-18 a sensor is not required, but the claims merely require that a sensing takes place. Sensing may be done by a human in a non-empirical manner. Thus, the claims are open to a visual monitoring or a more or less vague perception or impression of the operator or on the bench chemical procedure monitored by the operator which may be interpreted as "sensing".

Also, in the preamble of claim 16, the method is described as being the screening of a bioactive agent; however, no bioactive agent appears in the body of the claim.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-9, 13-15 are rejected under 35 U.S.C. 102(b) as being

clearly anticipated by WO 94/06292 [IDS].

The claims are directed to a method of testing substances on an organ comprising: perfusing the organ with a first medical fluid, "exposing" the organ to a test substance, gathering data.

WO 94/06292 discloses a method of organ perfusion where physiological or pharmacological research, i.e. effects of compounds, may be performed on the organ. Upstream sensors and downstream sensors monitor the perfusate for characteristics of pH, electrolytes and other characteristics. The sensors generate signals and are transmitted in real time, stored for future analysis or both (page 12). Duplicate organs may be perfused with perfusate that differs in only one component (pages 15 and 17). The effect of the component may be measured by the characteristics of the perfusate or other means.

Claims 1-3, 9, 16-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 98/09166 [IDS].

The claimed method was discussed above.

WO 98/09166 discloses a method for perfusing an organ with an emulsion blood substitute, administering test compounds, analyzing the perfusate for the concentration of the test compounds, thereby determining the ability of the compound to effect absorption, distribution, metabolism, excretion and pharmacokinetics of the drug. While the reference does not specifically state that the organ will not be transplanted, the reference does not show transplantation of the organ tested. Therefore, one may infer that the intent was not to transplant the organ, but to test possible drugs for their effect on the organ.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the

differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/06292 [IDS] in combination with WO 96/298865 [IDS] and Wiley *et al.* [U] or Nakahara *et al.* [V].

The claims are directed to a method of testing substances on an organ comprising: perfusing the organ with a first medical fluid, "exposing" the organ to a test substance, gathering data. Dependent claims require the use of two medical fluids and the testing of an immunotoxin.

WO 94/06292 has been discussed above.

WO 96/298865 teach the use of two perfusates in a method of organ perfusion. The first is a crystalloid solution and the second is a blood based solution (pages 26, 27). Thus, it is known to perfuse an organ with a first fluid to remove residual blood and other fluids and then with a second fluid which is a blood based fluid. Also, pharmaceutical and physiological agents may be perfused (page 6).

Wiley *et al.* teach perfusion of an organ with two immunotoxins in a transplantation model.

Nakahara *et al.* suggest that immunotoxins might be useful for pretreatment of organ allografts.

The perfusion of an organ with an immunotoxin in the method of WO 94/06292 which teach the testing of compounds in an *ex vivo* organ perfusion method would have been obvious because such immunotoxins may be valuable

in organ transplantation methods as described by Wiley *et al.* or Nakahara *et al.* and thus may be tested in the method described in WO 94/06292 which invites the use of any test compound without restriction.

Further, the method of WO 94/06292 may be modified by the use of two distinct medical fluids as described in WO 96/298865 in the absence of evidence of criticality.

The step of determining that the organ will not be transplanted is merely a mental step without any objective criteria and is well within the purview of one of ordinary skill in the art. In fact, experimental models often do not demonstrate transplantation after the organ has been tested for responses to external stimuli such as test compounds.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). It is applicants' burden to indicate how amendments are supported by the ORIGINAL disclosure. Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to the office action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to be 'S. Saucier', with a stylized flourish extending to the right.

Sandra Saucier
Primary Examiner
Art Unit 1651